IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

DAVID YOUNG
1906 Fulton
Falls City, Nebraska 68355

Plaintiff,

v.

DEPUY ORTHOPAEDICS, INC.
Serve Registered Agent:
CT Corporation System
251 E. Ohio St., Suite 1100
Indianapolis, IN 46204

and

DEPUY, INC.
Serve Registered Agent:
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

and

DEPUY INTERNATIONAL LIMITED
Serve Registered Agent:
St. Anthonys Road
Beeston
Leeds West Yorkshire
LS11 8DT, United Kingdom

and

JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., AND JOHNSON & JOHNSON INTERNATIONAL
Serve Registered Agent:
M.H. Ullmann
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Defendants.

Case No.

In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation, MDL No. 2244

MDL Docket No. 3:11-md-02244-K

Judge Ed Kinkeade

JURY TRIAL DEMANDED

COMPLAINT

PARTIES

1. Plaintiff David Young ("Plaintiff") states and brings this civil action before the Court for the United States District Court for the Northern District of Texas as a related action in the matter entitled In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation, MDL No. 2244. Plaintiff is filing this Complaint directly into the United States District Court for the Northern District of Texas as permitted by Case Management Order No. 1 of this Court.

2. Plaintiff is, and at all times relevant to this action was, a citizen of Nebraska and resides in Falls City, Nebraska. Plaintiff had a DePuy Pinnacle Acetabular Cup System ("Pinnacle Hip") surgically implanted into his body by an orthopaedic surgeon at the Jennie Edmundson Hospital located in Council Bluffs, Iowa.

3. Defendant DePuy Orthopaedics, Inc. ("DePuy") is and at all times relevant to this Complaint was, an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DePuy is and was at all times relevant herein doing business in and/or having directed its activities in Iowa.

4. Defendant DePuy, Inc. ("DePuy, Inc.") is and at all times relevant to this Complaint was, a Delaware Corporation with its registered agent listed as Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Defendant DePuy, Inc. is and was at all times relevant herein doing business in and/or having directed its activities in Iowa.

5. Defendant DePuy International Limited ("DePuy, Int'l") is and at all times relevant to this Complaint was, a United Kingdom Corporation which can be served at St. Anthonys Road, Beeston, Leeds West Yorkshire, LS11 8DT. Defendant DePuy, Int'l is and was at all times relevant herein doing business in and/or having directed its activities in Iowa.

6. Defendants Johnson & Johnson, Johnson & Johnson Services, Inc., and Johnson & Johnson International, ("J & J") are, and at all times relevant to this Complaint were, New Jersey Corporations with their principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J & J is and was at all times relevant herein doing business in and/or having directed its activities in Iowa.

7. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of its co-defendants.

JURISDICTION AND VENUE

8. This action is a civil action of which this Court has original jurisdiction under 28 U.S.C. § 1332 because it is a civil action between citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interests.

9. Venue of this case is appropriate in the Southern District Court of State of Iowa. Plaintiff states that but for Case Management Order No. 1 permitting direct filing into the Northern District of Texas, Plaintiff would have filed in the Southern District Court of State of Iowa. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

10. The Defendants are subject to personal jurisdiction in the Southern District Court of State of Iowa in that their product, the Pinnacle Hip, was placed in the stream of commerce with the reasonable expectation and intent that it be purchased by or on behalf of patients receiving treatment in the jurisdiction of the Southern District Court of State of Iowa, including Plaintiff, and Defendants intentionally and purposefully availed themselves to that jurisdiction in

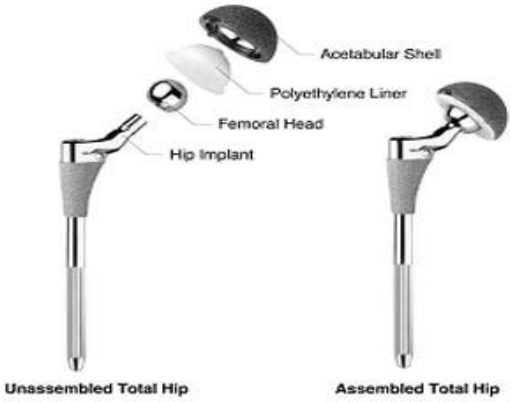
that they marketed and sold the Pinnacle Hip in the jurisdiction of the Southern District Court of State of Iowa.

FACTS OF THE OCCURRENCE

A. DePuy's Pinnacle Hip Is Unsafe and Has Not Been Adequately Tested

11. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

12. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem (labeled as "hip implant" in the diagram to the left), (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.



13. The Pinnacle Hip has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular liner. The design of the Pinnacle Hip was not

sufficiently tested by the Defendants, and it was never approved by the FDA as being safe or effective for the products' intended purpose.

14. The Pinnacle Hip is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

15. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle Hip, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

16. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

17. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

18. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – was not required to undergo premarket approval.

19. In addition, a medical device marketed *after* the MDA's effective may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (*i.e.*, a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then clear the new device for sale in the United States.

20. The MDA does not require an FDA determination that the device is in fact, substantially equivalent to a grandfathered device.

21. Instead of assuring the safety of the Pinnacle Hip through clinical trials, DePuy sought to market its Pinnacle Hip without conducting any clinical trials by obtaining FDA approval under section 510(k). To that end, Defendants submitted a section 510(k) premarket notification of intent to market the Pinnacle Hip.

22. By telling the FDA that the Pinnacle Hip's design was "substantially equivalent" to other hip products on the market, DePuy was able to avoid the safety review required for premarket approval under FDA regulations including clinical trials.

23. The FDA cleared the Pinnacle Hip for sale by means of the abbreviated 510(k) process and consequently, the FDA did not require the Pinnacle Hip to undergo clinical trials.

24. The 510(k) notification for the Pinnacle Hip includes only Defendant DePuy's assertion that it believes the DePuy Pinnacle Hip to be substantially equivalent to devices that themselves had never been reviewed for safety and effectiveness.

25. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny – or even clinical testing – of a device's safety and effectiveness.

26. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness. This point is forcefully underscored by the FDA's letter to DePuy, which says nothing about the safety and effectiveness of the Pinnacle Hip; finds only that the device was "substantially equivalent to devices introduced into interstate commerce prior to May 28, 1976"; and concludes by stressing that the agency's determination of substantial equivalence "does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies."

27. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the Pinnacle Hip's safety and effectiveness, but rather only a determination of equivalence to devices that themselves underwent no safety and effectiveness review.

28. While most hip replacements use a polyethylene ***plastic*** acetabular liner, DePuy's Pinnacle Hip has a critical difference: it uses a ***metal*** acetabular liner. By using a metal acetabular liner and a metal femoral ball, the Pinnacle Hip forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the Pinnacle Hip, hundreds of patients have been forced to undergo surgeries to replace the failed hip implants.

29. Plaintiff believes that the Pinnacle Hip suffers from a similar design or manufacturing defect that forced DePuy to recall over 93,000 metal-on-metal ASR and ASR XL hip implants. Both hip implants suffer from one or more similar design or manufacturing defects

that cause excessive amounts of cobalt and chromium to wear from the surface of the acetabular insert or from the femoral head. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

B. DePuy Should Have Recalled the Pinnacle Hip Years Ago; Over 1,300 Adverse Events Related To the Pinnacle Hip Have Been Reported

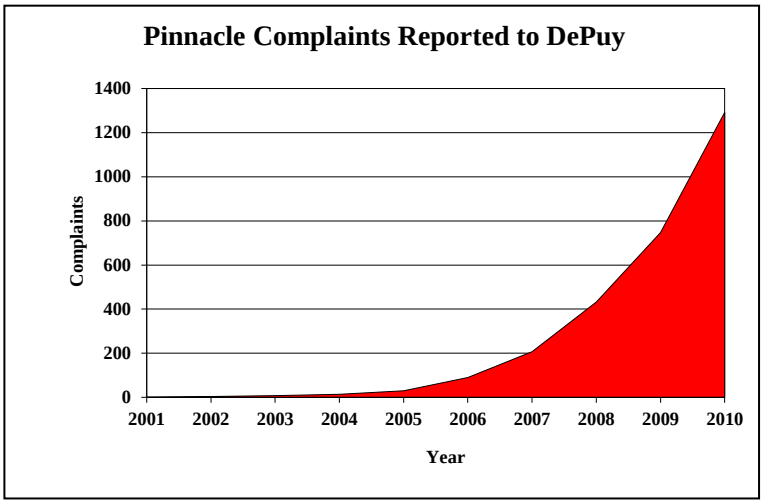
30. It was not long after DePuy launched the Pinnacle Hip that reports of failures began flooding into DePuy. For example, on May 4, 2002, DePuy received a complaint that a patient had to undergo a surgery to remove and replace the hip implant because the liner disassociated with the cup. DePuy closed its investigation of this complaint, finding that "corrective action is not indicated." Two weeks later, on May 17, 2002, DePuy received another report that another patient had to undergo surgery to remove and replace a defective hip implant because the acetabular cup had loosened. Again, DePuy closed its investigation of this complaint, finding that "corrective action is not indicated."

31. DePuy would go on to receive hundreds of similar complaints reporting that the Pinnacle Hip had failed due to premature loosening of the acetabular cup and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component.

32. By the time DePuy sold the Pinnacle Hip, DePuy had received numerous complaints related to the Pinnacle Hip. Consequently, DePuy was fully aware that the Pinnacle Hip was defective and that dozens of patients already had been injured by that defect. Based on this information, DePuy should have recalled the Pinnacle Hip before it was sold to the Plaintiff.

At minimum, DePuy should have stopped selling the defective implant when it became aware that it has catastrophically failed in several patients.

33. As the chart to the right shows, over the next two years, reports that the Pinnacle implant had failed were flooding into DePuy. For example, by the end of 2008, DePuy had received more than 430 reports and by the end of 2009, that number had skyrocketed to almost 750. To date, DePuy has received an astonishing ***1,300 reports*** associated with Pinnacle Hips.



34. Despite its knowledge that the Pinnacle hip had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, DePuy continued to sell the defective hip implant. In so doing, DePuy actively concealed the known defect from doctors and patients, including the Plaintiff and the Plaintiff's doctor, and misrepresented that that the Pinnacle Hip was a safe and effective medical device.

35. DePuy's reason to conceal the defect in its Pinnacle Hip is clear. In 2009 alone, DePuy brought in more than $5.4 billion in sales. Hip implant sales are critically important to DePuy's parent company, Johnson & Johnson, and DePuy is one of Johnson & Johnson's most profitable business groups. In 2008, DePuy was faced with a critical defect in one of its hip implant system. The last thing DePuy wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, DePuy

decided that it would not issue an embarrassing recall when it learned of the defects with its Pinnacle Hip. Moreover, motivated by greed rather than patient safety, DePuy did not even stop selling the Pinnacle Hip. Instead, it continued to manufacture the hip implants and it continued to sell them to unsuspecting patients like Plaintiff. To this day, DePuy continues to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

C. Plaintiff Has Suffered Injuries as a Result of the Pinnacle Hip

36. Plaintiff was implanted with the Pinnacle Hip on his right hip on or about September 22, 2003 at the Jennie Edmundson Hospital, in Council Bluffs, Iowa, by Dr. C. Kent Boese, M.D.

37. After the implantation, Plaintiff developed significant pain in the implanted hip which continues to this day.

38. Plaintiff has not yet scheduled an explantation of the Pinnacle Hip implant.

39. Plaintiff is now at an increased risk for requiring revision surgery in order to resolve his pain.

40. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

41. Plaintiff's recovery from the revision surgery would be long and painful. Plaintiff's injuries may be permanent, and they may cause additional complications in the future.

42. Plaintiff is also at increased risk for suffering from or in the future developing the toxic effects of the cobalt and chromium that have degraded from the defective Pinnacle Hip implant into his body.

43. As a direct and proximate result of the failure of his defective Pinnacle Hip and the Defendants' wrongful conduct, Plaintiff sustained and continues to suffer economic damages, severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the jurisdictional minimum of this court.

COUNT I – Negligence (Design, Manufacture and Sale)

44. Plaintiff incorporates by reference all allegations in all preceding paragraphs of this Complaint.

45. Defendants had a duty to exercise reasonable care in the design, formulation, manufacture, labeling, sale, and/or distribution of the Pinnacle Hip, including the duty to assure that the product does not cause users to suffer from unreasonable, dangerous side effects and symptoms.

46. Defendants were negligent in the development, design, testing, manufacturing, labeling, distribution and sale of the Pinnacle Hip in that:

A. The Pinnacle Hip implant design puts the metal femoral ball directly in contact with the metal liner, which is directly in contact with the metal acetabular cup which produces a large amount of metal on metal wear debris;

B. The Pinnacle Hip's unstable and defective design resulted in a hip prosthesis which had risks which exceeded the benefits of the medical device;

C. The Pinnacle Hip had a propensity for the acetabular cup to detach, disconnect, and/or loosen from the acetabulum, and for some patients to develop adverse reactions to high levels of metal debris generated by

normal use of the Pinnacle Hip;

D. The Pinnacle Hip's unstable and defective design resulted in a hip prosthesis which was more dangerous than the ordinary consumer would expect;

E. The acetabular component of the Pinnacle Hip has a low tolerance for malpositioning and is more difficult for the implanting surgeon to properly place or align in the acetabulum;

F. The Pinnacle Hip was improperly or inadequately designed with an unacceptably low sector angle which resulted in abnormal wear patterns leading to failure of bony ingrowths and hip instability;

G. DePuy failed to communicate information to Plaintiff's orthopedic surgeon about the increased failure rates and other significant problems, including those listed above, with the Pinnacle Hip.

47. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount that exceeds $75,000.00.

COUNT II – Negligence (Failure to Warn)

48. Plaintiff incorporates by reference all allegations in all preceding paragraphs of this Complaint as if fully set forth herein.

49. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Pinnacle Hip in its regular course of business and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Pinnacle Hip.

50. The Pinnacle Hip was unreasonably dangerous when put to the reasonably anticipated use of implantation during total hip replacement surgery without knowledge of its

increased risk for surgical complications.

51. Defendants' warnings to Plaintiff and Plaintiff's implanting physician about the dangers the Pinnacle Hip posed to consumers including Plaintiff were inadequate. Examples of the inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

A. Failed to accompany the Pinnacle Hip with proper warnings to the public and to orthopedic surgeons regarding all of the possible adverse side effects associated with its use including the increased difficulty to properly place or align the device in the acetabulum as compared to other devises;

B. Failed to provide adequate training and instructions to orthopedic surgeons and medical care providers for appropriate use of the Pinnacle Hip;

C. Failed to warn Plaintiff and the public before promoting the sale of the Pinnacle Hip, either directly or indirectly through third parties or related entities;

D. The Pinnacle Hip contained warnings insufficient to alert Plaintiff and Plaintiff's physician as to the risk of adverse events and/or reactions associated with the Pinnacle Hip, subjecting Plaintiff to risks which exceeded the benefits of the Pinnacle Hip;

E. The Pinnacle Hip contained misleading warnings emphasizing the efficacy of the Pinnacle Hip while downplaying the risks associated with it thereby making use of the Pinnacle Hip more dangerous than the ordinary consumer would expect;

F. The Pinnacle Hip contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through their prescribing physicians regarding the risk, scope, duration, and severity of the adverse reactions associated with the Pinnacle Hip;

G. The Pinnacle Hip did not disclose that it was inadequately tested;

H. The Pinnacle Hip failed to convey adequate post-marketing warnings regarding the risk, severity, scope and/or duration of the dangers posed by the Pinnacle Hip;

I. The Pinnacle Hip failed to contain instructions sufficient to alert consumers to the dangers they posed and to give them the information necessary to avoid or mitigate those dangers.

52. Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the Pinnacle Hip. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Pinnacle Hip and no patient, including Plaintiff, would have had the Pinnacle Hip implanted.

53. Defendants failed to provide timely and reasonable instructions and training concerning safe and effective use of the Pinnacle Hip to either Plaintiff or Plaintiff's physician.

54. The Pinnacle Hip, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instructions because Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Pinnacle Hip.

55. Defendants failed to perform or otherwise facilitate adequate testing, failed to reveal or concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data.

56. The Pinnacle Hip was surgically implanted into Plaintiff during the course of a total hip replacement in a manner reasonably anticipated by the Defendants.

57. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount that exceeds $75,000.00.

COUNT III – Strict Liability (Design Defect/Manufacturing Defect/Failure to Warn)

58. Plaintiff incorporates by reference all allegations in all preceding paragraphs of this Complaint as if fully set forth herein.

59. Defendants are the researchers, developers, designers, manufacturers, distributors, marketers, promoters, suppliers, and sellers of the Pinnacle Hip, which is defective and unreasonably dangerous.

60. At the time the Pinnacle Hip was sold it was then unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics.

61. The Pinnacle Hip is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

62. The Pinnacle Hip is defective in design in that it lacks efficacy, poses a greater likelihood of injury and is more dangerous than other available devices indicated for the same conditions and uses.

63. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the Pinnacle Hip did not outweigh its risks.

64. The Defendants herein failed to give adequate warning about the dangers posed by the Pinnacle Hip either to Plaintiff or Plaintiff's doctors.

65. The defective condition of the Pinnacle Hip rendered it unreasonably dangerous and/or not reasonably safe, and the Pinnacle Hip was in this defective condition at the time it left the hands of the Defendants.

66. The Pinnacle Hip was expected to and did reach Plaintiff and Plaintiff's physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

67. The Pinnacle Hip was surgically implanted into Plaintiff during the course of a

total hip replacement in a manner reasonably anticipated by the Defendants.

68. Defendants failed to use ordinary care to adequately warn of the increased risk of surgical complications associated with the use of the Pinnacle Hip for total hip replacement surgery.

69. Plaintiff was unaware of the significant hazards and defects in the Pinnacle Hip. The Pinnacle Hip was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary patient or physician. During the period that Plaintiff used the Pinnacle Hip, it was being utilized in a manner that was intended by Defendants. At the time Plaintiff had the Pinnacle Hip implanted it was represented to be safe and free from latent defects.

70. Plaintiff and Plaintiff's implanting physician did not have substantially the same knowledge as the Defendants or distributor. Specifically, DePuy had superior knowledge that the friction between the metal femoral head, metal liner, and metal acetabular cup could lead to the production of metal debris at the joint site.

71. Plaintiff suffered injury as a direct result of the DePuy Pinnacle Hip being sold in a defective manner and without proper and adequate warnings.

72. Defendants are strictly liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce the Pinnacle Hip, which was unreasonably dangerous for its reasonably foreseeable uses because of its design defects.

73. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount that exceeds $75,000.00.

COUNT IV – Breach of Express Warranty

74. Plaintiff incorporates by reference all allegations in all preceding paragraphs of this Complaint as if fully set forth herein.

75. Plaintiff purchased and Defendants sold the DePuy Pinnacle Hip implant referenced herein (or it was purchased on Plaintiff's behalf).

76. Defendants advertised, labeled, marketed, promoted, and sold its product, the Pinnacle Hip, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Pinnacle Hip would conform to the representations. More specifically, Defendants represented that the Pinnacle Hip was safe and effective for use by individuals such as Plaintiff or that it was safe and effective to treat Plaintiff's condition.

77. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and were a material factor in the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

78. Such statements were made with the purpose of inducing Plaintiff to purchase the Pinnacle Hip, or to induce others to purchase it on Plaintiff's behalf.

79. The Pinnacle Hip did not conform to the representations made by Defendant in that the Pinnacle Hip was not safe and effective and, in fact, had a known high failure and complication rate.

80. At all relevant times, Plaintiff used the Pinnacle Hip for the purpose and in the manner intended by Defendants.

81. Plaintiff and Plaintiff's physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

82. The breach of warranty was a substantial factor in bringing about Plaintiff's injuries.

83. Defendants have knowledge, actual or constructive, of such failure to conform.

84. As a direct and proximate result of the product's failure to conform, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount that exceeds $75,000.00.

COUNT V – Breach of Implied Warranty

85. Plaintiff incorporates by reference all allegations in all preceding paragraphs of this Complaint as if fully set forth herein.

86. Plaintiff purchased and Defendants sold the DePuy Pinnacle Hip implant referenced herein (or it was purchased on Plaintiff's behalf).

87. Defendants advertised, labeled, marketed, promoted, and sold its product, the Pinnacle Hip, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an implied warranty that the Pinnacle Hip would conform to the representations. More specifically, Defendants represented that the Pinnacle Hip was safe and effective for use by individuals such as Plaintiff or that it was safe and effective to treat Plaintiff's condition.

88. The Pinnacle Hip was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Pinnacle Hip minimally safe for its intended purpose.

89. At all relevant times, Plaintiff used the Pinnacle Hip for the purpose and in the manner intended by Defendants.

90. Plaintiff and Plaintiff's physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

91. Defendants' breach of the implied warranty was a substantial factor in bringing about Plaintiff's injuries.

92. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount that exceeds $75,000.00.

COUNT VII – (Fraud/Misrepresentation/Concealment)

93. Plaintiff incorporates by reference all allegations in all preceding paragraphs of this Complaint as if fully set forth herein.

94. Defendants, having undertaken the manufacturing, marketing, dispensing, distribution and promotion of the Pinnacle Hip, owed a duty not to deceive the Plaintiff, health care providers, and the public regarding the character, safety, quality and/or effectiveness of their medical devices.

95. Defendants through studies and reports received notice that their Pinnacle Hip was prone to premature failure and were causing patients to experience additional pain and injury. Defendants were informed that the metal-on-metal design of the Pinnacle Hip was capable of producing large volumes of metallic debris as the femoral head rotated and rubbed against the metal liner, which in turn rotated and rubbed against the acetabular cup. Defendants were aware that these particles had been known to damage muscles, tendons and other soft tissue; were aware that many of these complications had necessitated early removal of the Pinnacle Hip and that the complications might make these revisions more complicated.

96. Despite this knowledge, Defendants continued to manufacture, distribute and

promote the sale of the Pinnacle Hip and willfully deceived Plaintiff as to the health risks associated therewith.

97. Defendants willfully concealed, misrepresented, suppressed, and omitted scientific material and medical information about the risks of the Pinnacle Hip with the intent to defraud Plaintiff.

98. Plaintiff was unaware and ignorant of the falsity and/or incompleteness of the statements made by Defendants and reasonably relied upon them to be true.

99. Plaintiff directly and/or indirectly reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

100. As a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff suffered injury, as set forth herein, and is at an increased risk of developing serious side effects including, but not limited to, prosthesis joint dislocation, disconnection, creation of metallic debris and/or loosening, pain, disability, unnecessary and additional surgeries, and other injuries presently undiagnosed.

101. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and attorney fees and Defendants are liable to Plaintiff in an amount that exceeds $75,000.00.

COUNT VIII – Punitive Damages

102. Plaintiff incorporates by reference all allegations in all preceding paragraphs of this Complaint as if fully set forth herein.

103. Plaintiff is entitled to punitive damages because the Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false

representations about the safety and efficacy of the Pinnacle Hip and by failing to provide adequate instructions and training concerning its use.

104. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Pinnacle Hip despite available information demonstrating that the Pinnacle Hip could loosen and separate, causing serious harm to patients. Such risks and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious risks associated with the Pinnacle Hip or provided proper training and instruction to physicians regarding use of the Pinnacle Hip.

105. Defendants' misrepresentations included knowingly withholding material information from the FDA, the medical community and the public, including Plaintiff, concerning the safety of the Pinnacle Hip.

106. Defendants were or should have been in possession of evidence demonstrating that the Pinnacle Hip caused serious side effects. Nevertheless, Defendants continued to manufacture and market the Pinnacle Hip by providing false and misleading information with regard to its safety and efficacy.

107. Defendants failed to provide warnings that would have dissuaded health care professionals from using the Pinnacle Hip, thus preventing health care professionals and consumers, including Plaintiff, from weighing the true risks against the benefits of using the Pinnacle Hip.

108. Defendants failed to provide adequate training and instructions to physicians that could have prevented failure of the Pinnacle Hip causing serious harm and suffering to patients, including Plaintiff.

109. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered

and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount that exceeds $75,000.00.

JOINT ENTERPRISE AND/ OR JOINT VENTURE AND/OR CONCERTED ACTION

110. Each of the Defendants engaged in an agreement with one another for profit for the common purpose of designing, manufacturing, marketing, labeling, advertising, and selling the Pinnacle Hip.

111. The Defendants shared a common or community of pecuniary interest in deriving a profit from the sale of the Pinnacle Hip.

112. Each of the Defendants had an equal right and voice in the direction of the designing, manufacturing, marketing, labeling, advertising, and selling of the Pinnacle Hip and therefore had an equal right of control.

113. As a result of this joint enterprise and/or joint venture and/or concerted action the negligence of any Defendant is imputed to the other Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for:

A. Judgment in favor of Plaintiff and against all Defendants, for damages in such amounts as may be proven at trial

B. Compensation for non-economic losses, including, but not limited to disfigurement, physical, mental, and emotional pain and suffering as well as mental anguish and emotional distress in such amounts as may be proven at trial;

C. Compensation for economic losses including, but not limited to, past and future lost wages, past and future medical expenses, expenses for assistive care, durable medical goods and assistive devices, and other economic expenses in such amounts as may be proven at trial;

D. Restitution and disgorgement of all revenue that Defendants have obtained through the manufacture, marketing, sale, and administration of the

Pinnacle Hip;

E. Requiring Defendants to pay the reasonable attorneys' fees and costs of Plaintiff;

F. Requiring Defendants to pay pre-judgment and post-judgment interest;

G. Requiring Defendants to pay punitive or exemplary damages; and

H. Such other and further relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Date: October 25, 2011

Respectfully Submitted,

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